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EXAMINER	
ORWIG, KEVIN S	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,953	FABO, TOMAS	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8, 17, and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-16, 19, and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/05, 2/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed 19 October 2008 has been entered in full.

Status of the Claims

2. Claims 1-20 are currently pending.

Election/Restrictions

3. Applicant's election with traverse of Group II in the reply filed on Oct. 15, 2008 is acknowledged.

The traversal is on the ground(s) that the cited reference (POCKNELL) does not teach all the limitations of the claims and that the international search report did not indicate a lack of unity. The traversal is not found persuasive. Applicant's comments regarding Pocknell are acknowledged. While Pocknell does not teach an adherent elastomer, the instant inventions still lack unity and the restriction requirement is maintained in view of the references and rejections set forth below. The restriction is proper because there are two inventions, one drawn to a preparation, and one drawn to a method. Group I is drawn to a different statutory category of invention (a composition of matter) than Group II, which is drawn to a method. While related by the claimed preparation, the two inventions are not so closely related as to depend absolutely upon one another and are therefore patentably distinct. Further, as discussed below, Guyuron (U.S. 6,471,985) teaches a viscous silicone composition that cures by crosslinking after application to the skin. The resulting elastomer is adherent.

Therefore, the invention does not involve a novel composition and the inventions do not share a common special technical feature.

Regarding applicant's allegation that unity of invention is satisfied in light of the international search report, it is noted that the USPTO is not bound by the findings of the international searcher. Furthermore, it is noted the EPC examination report for the corresponding European Application included in the current application file shows that the subject matter of the instant invention is not new (page 3) and that at least some of the claims lack an inventive step (page 4). Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

4. Claims 1-8, 17, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Oct. 15, 2008.

5. Claims 9-16, 19 and 20 are under consideration.

Claim Objections

6. Claim 11 is objected to because of the following informalities:

Claim 11 is objected to in the recitation “The method as claimed in claim, characterized…”. Applicants' deletion of the base claim(s) from which claim 11 depends (i.e., [[9 or 10]]) (see 37 CFR 1.121) is acknowledged, however, the claim has not been amended to depend from another claim. For purposes of this Office Action, claim 9 is being interpreted as depending from claim 9 or claim10.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-13 and 19-20 are indefinite in the recitation "such as a stoma bag, a tube or parts of a wound dressing or a bandage" in claims 11 and 19. The phrase “such as” renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention is a limitation or whether it is merely listing disclosed examples and/or embodiments. Similarly, it is unclear whether the phrase "i.e. that side which faces away from the skin" is a limitation. Description of examples or preferences is properly set forth in the specification rather than the claims. Since it is unclear whether these phrases are limitations, and thus part of the claimed invention, these phrases render the claim indefinite. See MPEP § 2173.05(d).

Priority

8. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Swedish application (SWEDEN 030167603, filed 6/10/2003) was filed with the USPTO on Oct. 19, 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 9, 10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUYURON (U.S. 6,471,985; Issued Oct. 29, 2002).** Guyuron

discloses a method of treating a skin wound involving applying to the wound a room temperature vulcanizing (RTV) silicone composition comprising a crosslinkable polymer, and permitting the composition to cure to form a protective membrane (abstract). Guyuron teaches a method of applying to a wound a preparation comprising a silicone composition (column 1, lines 54-56; claims 1 and 21), at least one portion of which is in the form of a gel having a viscosity of about 60,000 to about 120,000 cps (equivalent to 60-120 Pa•s) (column 10, lines 20-25). Guyuron further teaches that suitable polysiloxanes for the invention range in viscosity from about 0.01 Pa•s to 2500 Pa•s (column 3, lines 19-26). It is noted that the preferred Formula I taught by Guyuron is a vinyl-substituted polydimethylsiloxane (column 3, lines 30-65, particularly lines 64-65; claim 3), which is the same compound preferred in the instant application (paragraph [0017]). Thus, the preparation comprises a composition that is "highly viscous" according to the definition set forth in paragraph [0017] of the instant specification. Furthermore, Guyuron teaches that the composition cures by means of crosslinking after application (column 2, lines 1-9). The cured composition is a skin-friendly elastomer (claims 2 and 22) and adheres to the skin (column 1, lines 59 and 60). Guyuron does not explicitly disclose the softness of the compositions in terms of the measurements defined in paragraphs [0041] and [0068] of the instant application, However, Guyuron teaches the amount of the crosslinkable polysiloxane component varies depending on the desired physical properties of the RTV silicone composition (such as the desired uncured viscosity and cured hardness) (column 4, lines 41-44). Additionally, Guyuron teaches that suitable wound dressings must stretch/flex to

accommodate skin or bodily movement and that the compositions of the invention are flexible when cured (column 1, lines 27-28; column 10, lines 48-49). It is well within the prevue of the ordinary artisan to adjust the amount of the crosslinkable polysiloxane component, as taught by Guyuron depending on the desired physical properties of the composition, both cured and uncured. Since Guyuron teaches that the uncured composition has a viscosity that meets the limitations of being "highly viscous" according to the instant specification, and teaches a final cured preparation that is flexible to skin and body movements, it is likely that the compositions of Guyuron meet this limitation as well. However, in the absence of an explicit teaching of the softness of the composition, it would have been *prima facie* obvious to the ordinary artisan to optimize the softness by adjusting the amount of crosslinkable polysiloxane and other components as taught by Guyuron. One would have been motivated to produce a final cured elastomeric preparation that is flexible since Guyuron teaches that such a property is necessary in these types of wound dressings, and such a composition would meet the limitation of "soft" according to the instant specification. Thus, the teachings of Guyuron render claim 9 obvious. Guyuron teaches applying the preparation in a thickness from about 0.1 mm to about 5 mm (abstract; column 2, lines 7-8; claim 1).Regarding claim 14, Guyuron teaches applying silicone composition to a wound (claim 1). It is well within the skill of an ordinary artisan to determine the precise amount and pattern of application optimal for a particular wound depending on the shape and nature of the wound. Thus, it would be *prima facie* obvious to an ordinary artisan to

apply the preparation around the outside edge of a wound in the range of 2-100 mm as is typical with other liquid bandages, ointments, and topical treatments known in the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

10. **Claims 9, 11-13, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guyuron in view of ABBER (U.S. 4,925,671; Issued May 15, 1990).**

Guyuron discloses the method of claims 9, 10, and 14, as applied above. For the purpose of this rejection, claim 11 has been interpreted to depend from claim 10, the preceding claim. Guyuron teaches that the silicone composition may be custom fit to any contoured or shaped surface. Guyuron also teaches that the compositions should be used in conjunction with a release agent when other objects are used to apply the composition (column 10, lines 41-46). Thus, the ordinary artisan would readily recognize that the composition of Guyuron would adhere to a variety of surfaces. While

clearly teaching that the composition is suitable as an adhesive, Guyuron does not teach the use of the composition as an adhesive for other medical articles *per se*.However, use of similar silicone compositions for this exact purpose was well known in the art at the time of the invention. For example, Abber discloses pressure sensitive adhesives comprising silicones including crosslinked vinyl-substituted dimethyl siloxanes (column 4, lines 37-43; column 7, lines 35-39). It is noted that these compositions have viscosities of about 20 Pa•s (column 4, lines 37-43) and are therefore "highly viscous" according to the instant specification. These compositions are intended for use as adhesives for various medical devices (abstract; column 1, line 11-16; claims 1-4). Since Guyuron suggests that the composition can be used on articles in addition to human skin, an ordinary artisan would readily have envisioned the use of the compositions taught by Guyuron as adhesives for a variety of medical devices as taught by Abber. Such a use amounts to combining known prior art elements (i.e. crosslinked silicone compositions) according to known methods (i.e. use of as these compositions as adhesives for medical devices) to yield predictable results (i.e. acceptable adhesion of the medical devices to the skin). The ordinary artisan would have had a high expectation of success in doing so since the prior art establishes that substantially identical compositions are useful for exactly the same purpose and since Guyuron suggests such a use. Thus, the combined teachings of Guyuron and Abber render claims 11 and 19 obvious.

Regarding claim 12, the limitation it would have been prima facie obvious to an ordinary artisan to apply the preparation of Guyuron to the article before applying it to

the skin (see the above discussion of claim 11). After doing so, placing the article to the skin would be applying the preparation to the skin at the same time as the article (i.e. applying them concurrently. Thus, the combined teachings of Guyuron and Abber render claim 12 obvious. Regarding claims 13 and 20, it is noted that Guyuron teaches a composition that is substantially identical to that which is instantly claimed. Thus, it is the examiner's position that the composition of Guyuron is also "designed such that its adherence to the article for medical use is greater than its adherence to skin after curing." Indeed, such is suggested by Guyuron since a release agent is required when using the composition with articles other than skin (column 10, lines 41-46), whereas the dressings of Guyuron possess releasability (e.g. they can be removed by gently peeling them off the skin) (column 11, lines 50-53), enabling non-damaging removal from a wound (column 1, lines 59-62). Furthermore, Abber teaches that the silicone adhesive of the invention are particularly suited to medical applications since it is easily removed from the skin, but has a high degree of adhesion over a prolonged period. Thus, even if the composition taught by Guyuron did not meet this limitation, it would have been *prima facie* obvious to design the composition to have these qualities per the teachings of Guyuron and Abber, rendering claims 13 and 20 obvious. Abber teaches that pressure-sensitive adhesives for use on human skin are used typically in bandages or other therapeutic devices which must adhere to the skin for a prescribed period of time and teach that the adhesive of the invention is useful for this purpose (column 1, lines 18-21; column 4, lines 64-66). Thus, it would have been *prima facie* obvious to an ordinary artisan to use the adhesive with a bandage (i.e. a wound dressing) or other

medical device per the teachings of Abber, rendering claim 15 obvious. Regarding claim 16, Abber teaches the use of the adhesive in conjunction with bandages such as transdermal therapeutic devices (abstract; column 2, lines 63-68). Abber describes some types of transdermal devices used with the adhesive as having semi-permeable layers with respect to the drug in the transdermal device (column 1, lines 48-50; column 4, lines 60-64), but clearly states that the adhesives have general applicability to essentially any transdermal device which must be adhesively placed in contact with the skin (column 5, lines 4-10). It is noted that the instant specification defines a liquid-tight dressing as merely having one layer that is liquid-tight (paragraph [0026]). Transdermal devices comprising at least one liquid-tight layer are well known in the art. An ordinary artisan would be motivated to use such a liquid-tight device in conjunction with the silicone adhesives taught by Guyuron because Guyuron teaches that the compositions act as barriers to retain moisture in the wound (column 10, lines 63-65; column 11, lines 16-18). Thus, to maintain such a moisture retentive property of a wound dressing, one would select a liquid-tight wound dressing for use with this adhesive, rendering claim 16 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary

skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO